Study Title:

A Clinical audit on the quality of care and the outcome of patients with Pregnancy Induced Hypertension within a Primary-Secondary care pathway: the Wesfleur-New Somerset Hospital Axis, Cape Town, South Africa.

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DECLARATION

I, Dr Theophilus Oluwadayo Sobamowo hereby declare that the work on which this dissertation is based is my original work and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

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Abstract

Background: Pregnancy Induced Hypertension (PIH) and its complications contribute to a significant burden of disease both in developed and developing countries of the world. Unfortunately, PIH has no cure, the delivery of the baby and the placenta is required. Early detection of pregnancy induced hypertension and close monitoring remains the key to achieving a favourable outcome. This study aimed to determine the quality of care given to women diagnosed with Pregnancy Induced Hypertension (PIH) within a care pathway spanning peri-urban primary and urban secondary level facilities.

Methods: This was a retrospective clinical audit of medical records of patients diagnosed with PIH. It was conducted in the Wesfleur -New Somerset Hospital drainage area, using a locally validated data extraction tool, based on the South African Maternal Care Guidelines. The data were analyzed using descriptive methods to report on the frequencies and proportions of the variables, and analyzed to report on statistical significance of correlations.

Results: The prevalence rate of pregnancy induced hypertension in this study was 12%.

The overall pregnancy induced hypertension complication prevalence in the study for mothers was 7.7%, and that of babies was 30.7%.

Facilities generally performed well according to the audit indicators detailing structures and processes that should be followed, as outlined by the standard guidelines used.

Two process indicators were correlated with adverse outcomes: 66.1% of patients were appropriately referred, resulting in statistically better foetal outcomes ($p = 0.059$); and those who booked early in the pregnancy had less PIH-induced complications than those who booked late ($p = 0.012$)

Conclusion: This study followed a standardized audit methodology and found that the quality of care in this peri-urban area is of a good standard and identified areas for quality improvement and further enquiry to ensure continual improvement in maternal and fetal outcomes.

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Abbreviations.

HERC – Human Research Ethics Committee

PIH – Pregnancy Induced Hypertension.

MgS04 – Magnesium Sulphate.

Chapter 1

Introduction

Maternal mortality is unacceptably high. About 830 women die from pregnancy or childbirth-related complications around the world every day. It was estimated that In 2015, roughly 303,000 women died during and following pregnancy and childbirth. Almost all of these deaths occurred in low-resource settings, and most could have been prevented (1).

Pregnancy induced hypertension (PIH) is a foremost cause of maternal death, with early detection and management being important to achieving favorable outcomes. PIH is the commonest pregnancy-induced complication affecting the mother-fetus dyad (2). Annually, it has been estimated that hypertensive disorders (HD) in pregnancy resulted into 50,000 maternal deaths, and the vast majority of them occurred in low-income or middle-income countries. Approximately 25% of the cases result in uterine growth restriction, and 15% result in preterm birth in developed countries (2). It predisposes the baby to fetal death, Abruptio placentae and fetal distress. The mother is predisposed to increased risk factor of cardiovascular diseases, renal failure, liver damage, pancreatitis, pulmonary edema, eclampsia, arrhythmia and type 2 diabetes in later life (3).

Epidemiology of pregnancy induced hypertension

Hypertensive disorders of pregnancy and its complications contribute to a significant burden of disease both in developed and developing countries of the world (4). According to the *Guidelines for Maternity Care in South Africa*, A manual for clinics, community health centers and district hospitals (fourth edition, 2015), the term "pregnancy induced hypertension" is defined as new onset of hypertension BP > 140/90mmhg, on two separates occasions at least 6 hours apart, occurring after 20weeks of gestation without significant proteinuria (5) . Pre-eclampsia and eclampsia are ranked second after hemorrhage as an explicit and direct cause of maternal death globally (4). The main causes leading to death were cerebral hemorrhage and pulmonary edema, therefore focus should be placed on the immediate lowering of acute severe hypertension and policy of restrictive fluid loading (6). Annually, about 500,000 babies died of the condition (7). In the developing countries, and in Africa in particular, these patterns tend to be repeated, and some instances, exaggerated.

In developing countries, the risk of a woman presenting with PIH is seven times higher compared to their counterparts in developed countries, and with 10-25% of these cases possibly resulting in maternal death, this represents an important preventable cause of maternal mortality and subsequent opportunity for intervention (8). In African studies, PIH occurred in 10% of pregnancies when compared to the global average of approximately 2% (9). A study conducted in Mulago Hospital (Kampala, Uganda) showed that the two major causes of maternal death were PIH and obstructed labor and their complications (9). In the developing world, severe forms of preeclampsia and eclampsia is common,

ranging from a low of 4% of all deliveries to as high as 18% in parts of Africa (10). By comparison, in the United State, preeclampsia and hypertensive disorders of pregnancy account for 5-8% of all births (10). In Zimbabwe, the maternal and perinatal mortality study conducted in 2007 found PIH to be a common causes of maternal mortality, and third highest reason for referral in labor (11). The effects of PIH on complications of pregnancy are well documented.

The selected maternal and newborn morbidities such as increased caesarean deliveries, abruptio placentae, and acute renal dysfunction, respiratory distress syndrome, ventilatory support, and fetal growth restriction were significantly greater in women with hypertension (11). PIH also contributes significantly to low birth weight. Women who delivered low birth weight babies were 5 times more likely to have developed pregnancy induced hypertension(11).

The local context of PIH care

According to the *Saving Mothers report 2014-2016: seventh triennial report on the confidential enquiries into maternal death in South Africa entered* by 15th May 2017 (12). there were 661 deaths in the last triennium (2014-2016) with an increase in the number of deaths of 21 since the 2011-2013 triennium (640); (12).

Maternal deaths due to Obstetric hemorrhage and hypertension in 2014-2016 accounted for 34.8% of all deaths (16.9% and 17.9% respectively (12).The report shows that poor quality of care is a leading cause of maternal death from pre-eclampsia (12). The report recommends controlling of high blood pressure in a high care setting, with close monitoring using standard methods outlined in the *Maternity care Guidelines of South Africa* (12). Understanding this burden of disease and extrapolating lessons from the global context could assist in improving maternal and fetal outcomes.

If one compares local figures with developed countries, indications are that pre-eclampsia is still a major global health concern. In the United Kingdom, hemorrhage accounted for 15% of Obstetric-related maternal deaths, while hypertensive disorders of pregnancy accounted for 10% (13). In California , maternal death resulting from preeclampsia /eclampsia amounted to 15%, while deaths secondary to obstetric hemorrhage amounted to 10% (14). High income countries have employed a strategy to reduce both the incidence of eclampsia and mortality associated with it by almost 90% by utilizing a combination of early detection during antenatal care and increased access to hospital care for women who developed preeclampsia (15).

Current knowledge of PIH

PIH has no cure, the delivery of the baby and the placenta is required. However, early diagnosis, active management of the blood pressure, and close observation is vital for controlling the condition during pregnancy(15).

To prevent any disease process, it requires a method for prediction of those at high risk for the disorder (16). It is recommended to have a clinical and biochemical test for prediction or early detection of PIH, but majority remain ineffective for general use in most developing countries (16). Some studies on uterine artery Doppler and first trimester maternal serum markers for early detection of PIH have been conducted, there is no convincing proof for general use in clinical practice, less so in resource poor settings (16). At present, no single reliable and cost effective screening test for pregnancy induced hypertension can be recommended for use (16).

Case finding is dependent on the presence of the diagnostic criteria: New onset of hypertension BP > 140 / 90mmhg, on two separates occasions at least 6 hours apart, presenting after 20weeks of gestation without significant proteinuria; the diagnosis of Pre-eclampsia (hypertension with significant proteinuria developing for the first time after 20weeks of gestation; or the presence of Eclampsia (patient experiences a generalized tonic-clonic seizure after 20 weeks of pregnancy and within 7 days after delivery, associated with hypertension and proteinuria) (12). The diagnosis is made when some biological damage has already occurred as evidenced by the clinical abnormal parameters, putting the mother-baby dyad at risk. To allow effective case finding, a number of important factors need to be addressed.

To tackle the problem of PIH effectively in any population by identifying those at risk and diagnosing early in the disease progression especially in poor under-resourced communities, a functional, accessible health care system is imperative (17). However, a significant number of developing countries particularly in Africa have limited health care access due to a number of factors, resulting in three levels of delay that is primary, secondary and tertiary level (17). There is a delay in the decision to seek care, poverty, and the rising cost of health care (17). Some socio-demographic factors play a vital role, for example, the level of education, the marital status and cultural beliefs which has aided maternal health-seeking behavior (18). Delay in reaching health facility or lack of access to quality of care has been the main obstacle to reducing maternal mortality in low-income countries (19). A study conducted in Nigeria showed that 50% of rural women live more than 5km from the nearest hospital, with no formal means of transportation except by walking even when in labor (19). A consequence of this phenomenon is that lack of access has contributed to high patronage of faith healing and alternative medical practitioners resulting in delays in referral which has accounted for 46.4% of all cases of eclampsia in this context (20).

It has been suggested that strengthening the health care system is vital in order to address this issue (21). Political commitment to mobilize necessary resources to the health sector with the view of improving the quality of emergency Obstetric services should be emphasized, it entails presence of a trained personnel, drugs, and equipment at every level of care (21). Access to emergency obstetric care should be prompt and affordable to limit delays when skills or facilities are lacking (21). A systematic approach to measuring these systemic issues is useful when considering quality improvement.

A quality improvement cycle aimed at improving the health care response to preeclampsia was carried out in California in 2013. The report shows that about 40% of patients with new onset of hypertension or new onset of proteinuria, in this study, went on to develop classic pre-eclampsia (22). The overall mortality rate for preeclampsia in this study was greater than 2 times that of the UK, largely due to differences in death caused by stroke (22). Controlling blood pressure was correctly seen as an important intervention to prevent deaths due to stroke in women with preeclampsia (22). The quality improvement analysis showed that despite clear triggers indicating serious deterioration in the patient's condition, health care professionals often failed to recognize and respond to these clinical signs in a timely manner (22). In fact, missed vital sign "triggers" occurred in 60% of the preeclampsia deaths (22). The health care professionals tended to minimize signs and symptoms and missed opportunities to alter the outcome (22). The conclusion from the study was that an organized tool to identify clinical signs or triggers could aid clinicians to recognize and respond in a more timely manner to avoid delays in diagnosis and treatment (22). A significant reduction in pregnancy induced hypertension was also seen in rural China and Sri Lanka. In 2011, Ronsman and Campbell showed that routinely screening pregnant women for hypertension and proteinuria is beneficial. Treating severe preeclamptic patients with antihypertensive and anticonvulsant drugs and, if necessary ending the pregnancy by inducing labor or carry out caesarean delivery is beneficial especially in low-income countries (23).

If the diagnosis of PIH is made at a community clinic, the *Guideline for Maternal Care in South Africa* stipulates that the advice of an experienced doctor should be obtained to establish if any immediate treatment, investigations, timing of referral and monitoring are required. The patient is checked for proteinuria, edema, and increased weight gain, to see if pre-eclampsia has developed in the meantime. If PIH is confirmed. The patient needs ultrasound assessment of the fetal well-being. Blood pressure should be controlled at values of 135-140mmhg systolic and 85-90mmhg diastolic (5). This entails the following:

- Patient may require antihypertensive therapy which is based on individual case. If needed for mild to moderate pre-eclampsia, methyldopa 250-500mg eight hourly orally is given.
- If patient is less than 38wks, can be managed on an outpatient basis at the high-risk antenatal clinic on a weekly basis and should be seen by the same experienced doctor or midwife at each visit. Delivery can be delayed until 39weeks if assessed by a specialist.

- If the patient with PIH develops proteinuria, increasing weight gain or there is decreased fetal movements, then she should be reassessed and delivered.
- Severe pre-eclampsia or imminent eclampsia patient should be stabilized and have immediate transfer to a specialist (regional or tertiary) hospital. Magnesium Sulphate (MgSO4) prophylaxis should be initiated against the development of seizures. Methyldopa 500mg should be administered orally. If acute severe hypertension [systolic >/= 160mmhg systolic, or Diastolic >/=110 mmHg], the patient should be given Nifedipine 10mg orally as a stat dose and monitored continuously until the ambulance arrives. A second dose of Nifedipine and MgSO4can be considered based on the patient's response.

Rationale for this study

While much epidemiological studies have been done in describing the burden of disease of pregnancy induced hypertension, few studies have looked at the quality improvement in antenatal care of patients with PIH. In urban Cape Town, South Africa, there is no documented attempt at improving the quality of care in this area. This study, in the form of a clinical audit, will be the basis of a quality improvement project in the antenatal care pathway for patients with PIH in the Wesfleur-New Somerset Hospital drainage area.

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Chapter 2: Publication-ready manuscript

Introduction and Literature review

Maternal mortality is alarming, with a significant amount of women dying from pregnancy or childbirth related complications around the world every day (1). Pregnancy induced hypertension (PIH) is a leading cause of maternal death, early diagnosis and management is the key to achieving favorable outcomes (2). Hypertensive disorders of pregnancy is responsible for a substantial burden of disease in developed and developing countries of the world. They are the leading cause of maternal and perinatal mortality and morbidity worldwide (3). In developing countries, the risk of a woman presenting with PIH is seven times higher compared to their counterparts in developed countries, this being a preventable cause of maternal mortality (4).

The recently published guidelines on the management of hypertensive disorders in pregnancy (HDP) highlighted the concerning trends in maternal deaths in South Africa (5). Although 78% of deaths occurred at a higher level of care, many of the emergencies are thought to have originated at the primary healthcare (PHC) or the district hospital (DH) level (5). Avoidable factors for HDP deaths were identified in 48% and 60% of the case at the Community Health Centre (CHC) and DH level, respectively(5). The factors identified at a PHC and DH included inadequate assessment, errors in diagnosis, delayed or no referrals to higher levels of care, non-adherence to management protocols, poor monitoring and poor response to abnormal monitoring(5).

Reproductive, maternal, newborn and child health has been a priority for both governments and civil society in low-and middle-income countries. This priorities was affirmed by world leaders in the millennium development goals (MDG) that called for countries to reduce child mortality by 67 percent between 1990 and 2015 (6). Although substantial progress on these targets has been made, few countries achieved the needed reductions. Poor reproductive health outcomes for women and their children may result from broad spectrum of morbid conditions and adverse circumstances and risk factors, such as unsafe sex leading to unwanted pregnancies and sexually transmitted infections, as well as violence against women and girls (6). In addition, the underlying causes of perinatal mortality includes maternal, fetal and health system factors.

Despite global progress in reducing maternal mortality, immediate action is required to begin making progress towards the ambitious sustainable development goals (SDG) and ultimately eliminating preventable maternal mortality (7).The year 2015 marks the start of the sustainable development goals (SDG) which include the global target of less than 70 maternal deaths per 100 000 live births globally by 2030 with no country exceeding twice the global MMR of 140 maternal deaths per 100 000 live births (7).

The projection suggest that the achievement of the SDG maternal mortality target would result in 60.1% fewer maternal deaths in the year 2030 and 1.4million fewer deaths cumulatively from 2016 to 2030

(7). The pay-off of achieving the SDG target is clear on the projected reduction in the number of maternal deaths, much work is needed at a country-level to accomplish this ambitious goal in the coming 15years (7).

The required acceleration will not be possible without a combination of interventions and actions taken, along the lines of the concerted efforts taken by countries that succeeded in bringing about a substantial maternal mortality decline in a short period of time (7). Each country context will be different, the ending of a preventable maternal mortality strategy suggests for adaptive, highly effective interventions to improve women's health before, during and after pregnancy (7).

Maternal factors shown to adversely affect pregnancy outcomes include maternal age (younger than 19yrs and older than 35yrs show increased complication rates), maternal infections, low nutritional status, low socio-economic and educational status, short inter-pregnancy interval (less than 2 years), rural residence, medical co-morbidities (Anemia, Diabetes Mellitus, HIV), and PIH-related complications. Most neonatal deaths are related to complications of birth asphyxia, low birth weight, septicemia, congenital malformation and preterm deliveries (6). Complications of undiagnosed and under-treated PIH impact on maternal and fetal outcomes negatively.

PIH is well documented to cause complications in mothers and in the fetus. Deaths from hypertensive disorders of pregnancy occur in all categories of hypertensive disorders with eclampsia and pre-eclampsia being the commonest final causes of death (5). The main causes leading to death were cerebral hemorrhage and pulmonary edema, therefore focus should be placed on the immediate lowering of acute severe hypertension and policy of restrictive fluid loading (5). Such steps will reduce the percentage of preventable deaths, assessed to be approximately 70% in the period 2014-2016 (5). Unfortunately, no progress has been made in the last decade in reducing the deaths due to hypertensive disorders of pregnancy (5).

The *saving mothers report on confidential enquiries into maternal deaths in South Africa* 2017: showed the following findings: Preterm Delivery rates 14.7%, IUGR 2.4%, Renal Failure 17.2%, Eclampsia 52.5%, HELLP Syndrome 12.9%, Pulmonary Edema 34.34%, Abruptio 6.3%, Fetal Death 24.4% (8). A prospective observation study was conducted in Obstetrics and Gynecology Department at Ghulam Muhammed Mahar Medical College and Hospital from Jan 1st to Dec 31st in Pakistan. PIH prevalence was 23.2%. The fetal complications include Preterm delivery 30%, Fetal Distress 20%, Intrauterine Death 27.3%, Low Birth Weight 30%, and IUGR 10%. Maternal complications includes Postpartum Hemorrhage PPH 29%, Pulmonary Edema 28.5%, and Placental Abruptio 47.3% (9). In comparison, Eclampsia, Pulmonary edema and Preterm delivery is still a major complication that needs attention.

Health system issues like impaired access to good quality antenatal, intrapartum and post-partum care have been identified as significant factors affecting pregnancy outcomes (6). The combined delivery of linked health interventions proved to be a more effective way of achieving common health goals than

working independently (6). To tackle the problem of PIH effectively in any population, an accessible, proactive, evidence-based health care system is imperative (10). In an African context, where delay in the decision to seek care, poverty, and the rising cost of health care impacts directly on pregnancy outcomes, this is an urgent project (10).

There are still significant shortcomings in the management of these life-threatening emergencies because of lack of skills and knowledge as evidenced in two local studies (11, 12).

Managing hypertensive disorders in pregnancy (HDP) requires knowledge and skills, and the best way to obtain such competencies is through educational initiatives such as Essential Steps in Managing Obstetric Emergencies (ESMOE) (13). Participating in regular emergency obstetric simulations (fire drills) at workplace allows primary care providers the opportunity to identify gaps in their knowledge and skills, and recognize and address shortcomings in equipment and drug stocks (13).

While much epidemiological studies have been done in describing the burden of disease of pregnancy induced hypertension, few studies have looked at quality improvement in antenatal care of patients with PIH. In urban and peri-urban Cape Town, South Africa, there is no documented attempt at improving the quality of care in this area. This study, in the form of a clinical audit, will be the basis of a quality improvement project in the antenatal care pathway for patients with PIH in the Wesfleur- New Somerset Hospital drainage area.

Aim and objectives

The aim of this study was to assess the quality of antenatal care for patients with PIH in the Wesfleur-New Somerset Hospital drainage area. This entails early identification of complications, with a subsequent significant decrease in the maternal and perinatal mortality rate.

In fulfilling this aim, the following objectives were set:

To describe the demographic profile of patients diagnosed with PIH.

To determine the prevalence of PIH.

To evaluate the standard of care at Basic Antenatal Care (BANC) sites. This includes documenting on the antenatal record chart, all clinical information and results of special investigations as well as changes that may occur during pregnancy, and the level of care that is needed. Each facility should have its own specific protocols for the management of obstetric conditions which must be in line with the South African national maternity care guidelines, it should be displaced in the facility.

To report on the outcomes of patients diagnosed with PIH.

Methodology

Study design

The study was designed as a retrospective review of clinical records using clinical audit methodology.

Study site

The study was conducted within the care pathway for pregnant patients in the Wesfleur Hospital (Atlantis)-New Somerset Hospital axis in Cape Town, South Africa, and included primary care antenatal sites providing Basic Antenatal Care (BANC) services in the Atlantis area. Atlantis is a peri-urban working-class community with a population of 67 491, with low socio-economic status (70% of households with a combined income of <R76 400/annum, with an average of 4.3 people/household), situated on the Western extreme of Cape Town, about 55km from the city centre. This area is served by a number of nurse-led primary care clinics. There is a small Family Physician-run hospital (Wesfleur Hospital) providing the only birthing unit in this area and 24hr emergency obstetric services. The secondary-level referral hospital, New Somerset Hospital, is about 50km away by road. In very specific emergencies, emergency helicopter services transport patients to the referral hospital (14).

Study population and sampling

The population being studied were women diagnosed with PIH in the specified geographic area. The sample for this study included all patients who had been diagnosed with PIH or any of its complications, at any level of care in the Primary care-Wesfleur-New Somerset care pathway over a 6- month period (March 2017 – August 2017). As all patients who fit the criteria were included, there was no need to use a sampling strategy. The exclusion criteria were patients with pre-existing chronic hypertension.

All patients who delivered within the 6- month study period, and fit the inclusion criteria, formed the study population. Birth registers at Wesfleur and New Somerset hospitals were used to compile a list of potential cases and clinical records accessed to confirm eligibility. A total of 65 eligible patients were identified, all of whom were enrolled in the study. A total of 541 births were recorded for this area during the period under review.

Data Collection and Analysis

An audit team comprising a Family Medicine registrar, two Family Medicine consultants, nursing and administrative staff at Wesfleur Hospital, was constituted. Specialist obstetricians within the referral network were asked to review and comment on various aspects of the project.

Prior to commencement of data collection, an audit tool was developed using the Donabedian approach of measuring Structure-Process-Outcome as separate domains (15). Face and content-validity was established by getting the tool reviewed by Senior Family Physicians and Obstetricians who are familiar with the Maternal Care Guidelines and are senior clinicians within the care pathway. Thereafter, a small

pilot study was conducted to test reliability. Using the finalised tool, the researcher extracted data from the folders directly onto an Excel spread sheet, transferred it to the statistics software, STATISTICA version 12 (16) for analysis by a biostatistician. The data is reported as means and confident intervals for each key outcome. Correlations were calculated between dependant variables (maternal and fetal complications) and independent variables (all other variables). Correlations were deemed significant when $p<0.05$.

Ethical Considerations

The National Health Act requires that an informed consent should be obtained from every research participant before the commencement of the research. However, as this is a retrospective audit of clinical records, consent to access the records was given by the hospital authorities.

In compliance with the World Medical Associations Declaration of Helsinki that states that every precaution must be taken to protect the privacy of research subjects and confidentiality of their personal information (17), all study data was anonymized and stored on a password protected computer that was only accessible to the research team.

Ethical Approval for the research proposal was obtained from the Human Research Ethics Committee (HREC ref.: 845/2017) of the University of Cape Town, and the Provincial Research Committee of the Department of Health, Western Cape Government, granted access approval. Permission to review the records was obtained from the hospital management and clinical staff being audited.

Results

During the study period (March 2017-Aug 2017), a total of 541deliveries were registered in the Atlantis area. Sixty-five (n=65) women were diagnosed with PIH and received related care in the Wesfleur-New Somerset Hospital Axis. All of them were included in this study. This gives a prevalence rate of 12% for PIH in this population. PIH maternal complications were recorded in 7.7% of the study population, while the fetal complications were documented in 30.7% of cases.

Those below the age of 20 formed 23.1% of the patients while those above 40 years accounted for 1.5%. As depicted in Table 1 below, maternity records showed that coloured patients formed majority of the sample (78.5%), followed by black patients (18.5%) with white and Indian patients accounting for the minority of the study (1.5% each). There was no indication in the clinical records to determine how these racial classifications were assigned. The majority of the women were unemployed (73.8%). More than three quarters of the patients were single (76.9%), 21.5% married, and 1 patient (1.5%) was divorced. 59 (90.8%) of the cohort were booked for antenatal care. Gravidity ranged from 1 to 5, with

primigravidae accounting for 47.6% (31/65) while 53.1% (34/65) were multi-gravida (2 or more previous pregnancies).

Table 1. Socio-demographic characteristics of the study sample

	Total sample N=65	
Variables	**N**	**%**
Age-group		
< 20yrs	**15**	**23.1**
20-29yrs	**25**	**38.5**
30-39yrs	**24**	**36.9**
40yrs and above	**1**	**1.5**
Race		
Black	**12**	**18.5**
White	**1**	**1.5**
Coloured	**51**	**78.5**
Indian	**1**	**1.5**
Marital status		
Single	**50**	**76.9**
Married	**14**	**21.5**
Divorced	**1**	**1.5**
Employment status		
Employed	**17**	**26.2**
Unemployed	**48**	**73.8**
Booking status		
Booked	**59**	**90.8**
Un-booked	**6**	**9.2**
Gravidity		
1	**31**	**47.6**
2	**12**	**18.8**
3	**11**	**17.2**
4	**4**	**6.3**
5	**7**	**10.9**

In Table 2 below, of the 65 pregnant patients 35.4% (23/65) smoked cigarettes. Very few had a comorbid condition (3.1%), although 16.9% (11/65) had a positive family history of hypertension, 3.1% (2/65) had documented family history of diabetes, and none had a family history of a combination of both. 36.9% (24/65) of the patients had a BMI less of 25 or lower, while 53.8% (35/65) had a BMI of 26 and above. Roughly one third of patients (35.4 %) had a previous history of obstetric complications. There were no twin pregnancies.

Table 2. Risk profile pattern of the study sample

	Total sample N= 65	
Variables	**N**	**%**
Smoking status		
Yes	**23**	**35.4**
No	**42**	**64.6**
Comorbid Condition		
Present	**2**	**3.1**
Absent	**63**	**96.9**
Family History		
Hypertension	**11**	**16.9**
Diabetes	**2**	**3.1**
Hypertension and Diabetes	**0**	**0**
BMI		
26 and above	**35**	**53.8**
25 and below	**24**	**36.9**
Unknown	**6**	**9.2**
Previous history of Obstetric Complication		
Yes	**23**	**35.4**
No	**42**	**64.6**

The structural indicators ascertained the availability of key resources needed to deliver antenatal services at a primary care facility. All primary care facilities in Atlantis (n=4) were audited for readiness to diagnose, treat and refer patients with PIH. It was found that all clinics had all the resources in place to deliver the service.

Table 3. Structure indicators of the audited facilities.

	Total facilities N=4	**%**
Copy of Clinical Practice Guideline available in the facility	**4**	**100**
Availability of equipment	**4**	**100**
For basic ANC		
BP machine and cuff sizes	**4**	**100**
Urine dipstix	**4**	**100**
Weighing scale	**4**	**100**
Tape - measure	**4**	**100**

Evaluation of the process indicators showed that high levels of compliance with best practice, as defined by the Maternal Care Guideline. There were lapses on timely referring patients with the condition. Only 66.1% of patients with the condition were timely referred. Also, majority of the delivery took place via caesarean section with the percentage of 52.3%. The total number of 6 women with PIH delivered at Wesfleur hospital and subsequently transferred to New Somerset Hospital for stabilisation, while 59 of the women with PIH had the delivery at New Somerset Hospital.

Table 4. Process indicators at Wesfleur Hospital Atlantis- New Somerset Hospital Axis.

Process indicator	**Total sample (n=65)**	**% completed and recorded**
Weight	**65**	**100**
Urine dipstix	**65**	**100**
Blood Pressure	**65**	**100**
Diagnosis based on clinical data	**65**	**100**
Appropriate referrals	**43**	**66.1**
Baseline investigation for		
Haemoglobin	**65**	**100**
Platelet	**65**	**100**
Creatinine	**65**	**100**
Urea	**65**	**100**
AST	**65**	**100**
Protein concentration in Urine		
1	**18**	**27.7**
2	**39**	**61.9**
3	**8**	**12.7**
Mode of delivery		
Vaginally	**31**	**47.7**
Caesarean section	**34**	**52.3**

Maternal complications occurred in 5 women, 4 of whom had more than one complication. As shown in Table 5, eclampsia occurred in 4.6%, renal complications in 7.7%, and pulmonary edema in 3.1% of the entire sample. Fetal complications as shown in Table 5, intrauterine growth restriction occurred in 12.3%, fetal distress in 26.2%, and preterm delivery in 23% of the entire sample. There were no maternal or fetal deaths in the current sample.

Table 5: Complications profile of the study sample

	Total sample N=65	%
Maternal complications		
Overall maternal complications	5	7.7
HELLP Syndrome	4	6.2
Eclampsia	3	4.6
Stroke	0	0

Renal Failure	5	7.7
Pulmonary Oedema	2	3.1
>1 complication	4	6.2
Maternal death	0	0
Fetal Complications		
Overall fetal complications	20	30.7
IUGR	8	12.3
Fetal Distress	17	26.2
Abruptio Placenta	0	0
Preterm Delivery	15	23
Fetal death	0	0

Booking status was significantly associated with PIH complications, in those not booked with p = 0.37 vs p = 0.012 in those being booked.

Understandably, delivery mode was significantly associated with fetal distress (p = 0.001), with 42.4% of distressed babies born via C-section compared to only 6.5% of babies born via vaginal birth.

No significant associations were found between presence of PIH and age (p = .881), employment (p = .778), relationship status (p = .333), gravidity (p = .831), smoking (p = .697), BMI (p = .626), previous obstetric complication (p = .697), or mode of delivery (p = .264).

Discussion

In this study, the prevalence of PIH was 12%. Globally, the PIH prevalence rates varies from country to country and has been reported to occur as low as 0.51% to as high as 38.4%(18) . In African studies, PIH occurred in 10% of pregnancies, which is significantly higher than the global average of approximately 2% (19). In South Africa, PIH prevalence was found in 18% of all pregnancies (5) . Two hospital based studies in sub-Saharan Africa had prevalence of 11.5 and 26.5%(20). In Ethiopia, the prevalence ranges from 1.2 % to 18.25% (21). In United States of America, 7-10% of all pregnancies are complicated by PIH (22). In China, it was estimated at 5.2%(23).

PIH prevalence rates in India was reported as 7.8% (24). while in Iran it was 9.8% (25). In Sweden, prevalence rates have been reported as 1.5% and 7.5% in Brazil (26, 27). The result of our study supported the conclusion that PIH prevalence is higher in developing countries when compared to developed countries. The reason being that access of women to antenatal care and emergency obstetric care is limited in developing country. Most women showed up in health facilities when symptoms are serious. The result from our study also showed a slight increase of 2% when compared to the average in African studies.

Given that prevalence rates elsewhere ranges from 2-20%, this low prevalence could represent a deficiency in the case finding methodology used (likely, as all women giving birth made use of the facilities in this study), an underdiagnosis by the attending clinicians (likely, as all facilities scored very well on clinical process indicators), or be a true reflection of this population's epidemiological profile. If this prevalence estimate is true, this population has one of the lowest rates reported in the literature anywhere in the world, and this would warrant further epidemiological investigation.

The prevalence of PIH complications is as follows: The overall maternal complications in our study was 7.7%, while that of fetal complications occurred in 30.7% of all children. This is comparable to the global picture, where about 10% of all women with PIH experience related complications (28).The prevalence is similar in Zimbabwe which accounts for 19.4% of pregnancies (29). The result from our study showed a slight reduction of 2.3% when compared to the global average.

The effects of inappropriate referral and un-booked patients diagnosed with PIH cannot be over emphasized. In this study, early booking was associated with lower complications (p= 0.012).This finding is corroborated by studies elsewhere in the world that found improved maternal (any PIH complication) and fetal outcomes (IUGR and intra-uterine death) due to early use of antenatal services. Similarly, appropriate referral was associated with improved fetal outcomes. This underscores the need for early booking in pregnancy for early identification and prompt management of problems.

The complication profile of our study showed two positive outcomes. There were no fetal or maternal deaths. The fetal complications were dominated by preterm delivery 38.5%, fetal distress 26.2% and IUGR 12.3%. On the other hand, maternal complications were favorably comparable to that found elsewhere in the developing world, as demonstrated in Table 6 below. The *Saving Mothers report on confidential enquiries into maternal deaths in South Africa* 2017: showed the findings Preterm Delivery 14.7%, IUGR 2.4%, Renal Failure 17.2%, Eclampsia 52.5%, HELLP Syndrome 12.9%, Pulmonary Edema 34.34%, Abruptio 6.3%, Fetal Death 24.4%(8). In Ethiopia, a prospective study was carried out in the referral hospital at Mettu Karl, it recorded the following maternal outcomes: Renal failure 7%, Abruptio 2%, Liver failure 12%, HELLP 12.4%, Eclampsia 19%, while the unfavorable fetal outcomes were preterm delivery at 31%, fetal distress 18.5%, with no maternal and fetal deaths reported (30) . The outcomes of another prospective study which reviewed 112 deliveries with PIH conducted in Pakistan are as follows: pulmonary edema 28.5%, Abruptio was 47.3%, fetal distress 20%, IUGR 10%, preterm delivery 30% ,Eclampsia 15.8%, HELLP Syndrome 8.3% (9). However a prospective study conducted in India recorded both maternal and fetal mortalities with the following maternal outcomes: 2.12% maternal death, 6.3% renal failure, HELLP 10.63%, Eclampsia 9.8% the fetal outcome were as follows: 19.14% had IUGR, fetal distress 24.19 % (31). A retrospective case control study was conducted in Taiwan on women with PIH , the outcome was Preterm delivery 77.7%, Renal failure

1.23%, Eclampsia 9.37%, Pulmonary Edema 2.38%, HELLP Syndrome 9.3%, Abruptio 4.96%, Maternal death 1%, Fetal death 8.82% (32). A retrospective study was conducted in Haiti in women with PIH, the findings showed Preterm delivery 15.6%, Fetal distress 20%, IUGR 10%, Eclampsia 23.3%, Pulmonary Edema 28.5%, Abruptio 47.3%, Maternal death 0.3%, Fetal death 4.9% (33). An analytical cross sectional study was conducted in Zimbabwe on women with PIH, the findings was preterm delivery 14.3%, Eclampsia 2.1%, Fetal death 5.4% (29).

Prematurity was more frequent among women with pregnancy induced hypertension PIH. The present study result showed no stillbirth, but highlighted prematurity, fetal distress as the main perinatal consequences.

A prospective study done in Ethiopia, Pakistan and the retrospective study in Taiwan observed similar patterns in perinatal outcomes. This is in contrast to study done in Haiti and Zimbabwe with lower percentage. Prematurity increases perinatal morbidity and mortality rates with possible immediate or late sequels, this indicate a room for improvement and suggest that optimal care delivered in a low-resource setting should continue to be an important focus for future clinical studies.

In this study, no maternal death was recorded. This is in conformity with the study conducted in Ethiopia, Pakistan. A minimal percentage was recorded in Haiti, Taiwan, and India.

In contrast to other studies done in Ethiopia, Pakistan, Haiti where majority of patients had Eclampsia, we found out that small percentage in our study had Eclampsia. This is in consistent with the study conducted in Zimbabwe, India, Taiwan.

Table 6: Complications profile comparison with other countries:

	This study	Saving Mothers Report (2017)	Ethiopia	Pakistan	India	Taiwan	Haiti	Zimbabwe
Preterm Delivery	38.5%	14.7	31%	30%	NR	77.7	15.6	14.3
Fetal Distress	26.2%	NR	18.5%	20%	24.19%	NR	20	NR
IUGR	12.3%	2.4	NR	10%	19.14%	NR	10	NR
Renal Failure	7.7%	17.2	7	NR	6.3%	1.23	NR	NR
Eclampsia	4.6%	52.5	19%	15.8%	9.8%	9.37	23.3	2.1
HELLP Syndrome	6.2%	12.9	12.4%	8.3%	10.63%	9.3	NR	NR
Pulmonary Edema	3.1%	34.34	NR	28.5%	NR	2.38	28.5	NR

Abruptio	0	6.3	2%	47.3%	NR	4.96	47.3	NR
Liver Failure	0	NR	12%	NR	NR	NR	NR	NR
Maternal Death	0	NR	0	0	2.12%	1	0.3	NR
Fetal death	0	24.4	NR	NR	NR	8.82	4.9	5.4

Strengths

The study documented care along a pathway and did not restrict its focus to a single facility only. This represents a novel approach to clinical audit, providing rationale for good quality primary care in terms of accessibility, decision-making and efficient referral. In addition, this is the first time that a study has evaluated a peri-urban to urban clinical pathway for this high-risk group of patients.

A standardized methodology was implemented in the study design, and national guidelines were used to develop a data collection tool, making this a valid and reliable study for reproduction in other parts of South Africa.

Although the study sample was small, it represented the entirety of the population at risk, and the findings can therefore reliably be used to comment on the quality of services in this area.

Limitations

In any study whose data is derived from clinical records, the completeness of the dataset is dependent on the completeness of the clinical record. As such, the data quality of the study may have been adversely affected.

The nature of clinical audits is that they are site-specific and cannot be extrapolated to the general population. However, it must be added that generalisation is never the aim of a study of this nature, rather it is to provide commentary on the quality of the clinical services.

Many of the outcomes described in this study can be multifactorial. To determine if they are definitively related to the presence of PIH, a much larger sample size would be needed, and data analysis would need to include multiple logistic regression to determine correlations.

While the review of the clinical records was thorough, this study did not do any longer- term follow-up on any of the patients. This would have provided additional useful information about the long-term sequelae of PIH-related complications.

Recommendations:

Future research should explore system deficiencies related to delayed referral and inadequate record keeping in more details, with particular attention to the resources allocated to maternity services, as well as the subjective experiences of staff working in these services.

Late or non-booking by patients is a perennial problem and warrants research attention to understand contextual and personal factors impacting patient decision-making and health-seeking behaviour.

Conclusion

Hypertensive disorders of pregnancy constitute a substantial burden of disease in both developed and developing countries of the world, with significant pregnancy complications.

The structural indicators ascertained the availability of key resources needed to deliver antenatal services at primary care facility. The evaluation of the process indicators showed that high levels of compliance with best practice, as defined by the maternal care guideline.

The complication profile of our study showed two positive outcomes. There were no fetal or maternal deaths. Two process indicators were correlated with adverse outcomes: 66.1% of patients were appropriately referred, resulting in statistically better fetal outcomes. ($p=0.059$) and those who booked early in the pregnancy had less PIH complications than those who booked late ($p=0.012$).

We piloted a useful audit tool to assess quality of district-level care in patients with PIH, showing that in the study site a decent quality of care is being delivered, despite significant resource challenges.

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Appendix A

Data extraction tool:

VARIABLES	Coding
AGE GROUP	
< 20yrs	1
20-29yrs	2
30-39yrs	3
40yrs and above	4
RACE	
Black	1
White	2
Colored	3
Indian	4
MARITAL STATUS	
Single	1
Married	2
Divorced	3
Widowed	4
BOOKING STATUS	
Booked	1
Un-booked	0
EMPOLYMENT STATUS	
Yes	1
No	0
SMOKING STATUS	
Yes	1
No	0
FAMILY HISTORY OF HYPERTENSION	
Yes	1
No	0
DIABETES	
Yes	1
No	0
HYPERTENSION AND DIABETES	
Yes	1
No	0
PRE-EXISTING RENAL DISEASE	
Yes	1
No	0
ANY OTHER CHRONIC DISEASE	
Yes	1
No	0

BODY MASS INDEX (BMI)

< 25	1
25 and above	2
Unknown	3

GRAVIDITY

1
2
3
4
5 and above

PREVIOUS OBSTETRIC COMPLICATION

Yes	1
No	0

STRUCTURE

(1) Any available standard guideline to manage patients with PIH AT MOU?

Yes	1
No	0

(2) **Availability of equipment for basic ANC**

(a**)Blood Pressure Machine and cuff sizes**

Yes	1
No	0

(b)**Urine Dipstix**

Yes	1
No	0

(C) W**eighing Scale**

Yes	1
No	0

(d) **Tape measure**

Yes	1
No	0

PROCESS

(1) Was the patient checked for the following each visit?

(a) Weight

Yes	1
No	0

(b) Urine dipstix

Yes	1
No	0

(c) Blood Pressure

Yes	1

No 0

(2) **Was diagnosis based on available clinical data?**

Yes 1

No 0

(3) Was appropriate referral made on those diagnosed with PIH?

Yes 1

No 0

(4) Was basic investigations done for patients with PIH?

(a) Hemoglobin

Yes 1

NO 0

(b) Platelet

Yes 1

No 0

(c) Creatinine

Yes 1

No 0

(d) Urea

Yes 1

No 0

(e) AST

Yes 1

No 0

OUTCOME

Diastolic Blood Pressure

90-109 mmhg 1

110 or more 2

PROTEIN CONCENRTATION IN URINE

1

2

3

4

MODE OF DELIVERY

NVD 1

C/S 2

(1) Were any maternal complications documented?

(a) Eclampsia

Yes 1

No 0

(b) Stroke

Yes 1

No 0

(c) HELLP Syndrome

Yes 1

No 0

(d) Renal Failure

Yes 1

No 0

(e) Pulmonary Oedema

Yes 1

No 0

(f) Maternal Death

Yes 1

No 0

(2) Were any fetal complications documented?

(a) Intrauterine growth restriction

Yes 1

No 0

(b) Fetal Distress

Yes 1

No 0

(c) Abruptio Placentae

Yes 1

No 0

(e) Fetal Death

Yes 1

No 0

Appendix B

Permission letter to access patient's record

13th October 2017.

The Facility Manager,

New Somerset Hospital,

Cape Town.

RE: REQUEST FOR PERMISSION TO ACCESS THE PATIENTS FOLDER.

Dear Sir,

I humbly write to seek your permission to carry out the research project on the clinical audit on the quality of care and the outcome of patients with Pregnancy Induced Hypertension in Wesfleur Hospital Atlantis- New Somerset Hospital axis, Cape Town.

This is retrospective clinical audit that will involve reviewing of medical records of patient seen between March 2017- August 2017.

The research will be conducted in accordance with the regulations of Health Research Ethics Committee (HREC).

I am looking forward to your favourable consideration.

Thank you.

Signature removed to avoid exposure online

DR T.O SOBAMOWO

Family Medicine and Primary Care,

University of Cape Town.

Appendix c

Human Research Ethics Committee Approval

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room E53-46 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6626
Email: shureita.thomas@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

05 December 2017

HREC REF: 845/2017

Dr Tasleem Ras
Family Medicine
Falmouth Building

Dear Dr Ras

PROJECT TITLE: CLINICAL AUDIT ON THE QUALITY OF CARE AND THE OUTCOME OF PATIENTS WITH GESTATIONAL PROTEINURIC HYPERTENSION IN WESFLEUR HOSPITAL ATLANTIS - NEW SOMERSET HOSPITAL AXIS CAPE TOWN, SOUTH AFRICA (MMED CANDIDATE - DR T SOBAMOWO)

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30 December 2018.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

Please quote the HREC REF in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

The HREC acknowledge that the student, Dr Theophilus Oluwadayo will also be involved in this study.

Yours sincerely

Signature removed to avoid exposure online

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE
Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938

HREC 845/2017

This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH 2006), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI),and Declaration of Helsinki (2013) guidelines.
The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

HREC 845/2017